IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MISSOURI WESTERN DIVISION

CERNER CORPORATION,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**Case No. 04-1033-CV-W-GAF**
	)	
VISICU, INC.,	)	
	)	
Defendant.	)	

FINDINGS OF FACT AND CONCLUSIONS OF LAW

A. General Standards

1. Cerner must prove both materiality and intent to deceive by clear and convincing evidence. *See Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008); *Pressure Prods. Med. Supplies v. Greatbatch Ltd.*, 599 F.3d 1308, 1320 (Fed. Cir. 2010) (emphasizing the "specific and demanding showings of evidence" that inequitable conduct claims require).

2. As the party alleging inequitable conduct, Cerner must prove that "the applicant (1) made an affirmative misrepresentation of material fact, failed to disclose material information, or submitted false material information, and (2) did so with intent to deceive the PTO." *Purdue Pharma Prods. L.P. v. Par Pharm., Inc.*, Nos. 2009-1553, 2009-1592, 2010 WL 2203101, at *4 (Fed. Cir. June 3, 2010) (citing *Star Scientific*, 537 F.3d at 1365).

3. Importantly, "at least a threshold level of each element – *i.e.*, both materiality and intent to deceive – must be proven by clear and convincing evidence." *Star Scientific*, 537 F.3d at 1365.

4. "[E]ven if this elevated evidentiary burden is met as to both elements, the district court must still balance the equities to determine whether the applicant's conduct before the PTO was egregious enough to warrant holding the entire patent unenforceable." *Id.* (citation omitted); *see also Optium Corp. v. Emcore Corp.*, 603 F.3d 1313, 1320 (Fed. Cir. 2010) (same); *Astrazeneca Pharm. LP v. Teva Pharm. U.S., Inc.*, 583 F.3d 766, 776 (Fed. Cir. 2009) (noting the court must balance findings of materiality and intent where threshold levels for both are met).

5. If Cerner does not establish "a threshold level of intent to deceive or materiality . . . by clear and convincing evidence, the district court does not have any discretion to exercise and cannot hold the patent unenforceable regardless of the relative equities

or how it might balance them." *Star Scientific*, 537 F.3d at 1367; *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1358 (Fed. Cir. 2008) (citation omitted).

B. Materiality

6. In assessing materiality, courts are guided by PTO Rule 56 and the "reasonable examiner" standard. *Rentrop v. Spectranetics Corp*., 550 F.3d 1112, 1119 (Fed. Cir. 2008). Rule 56 provides that information is material only if it either establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim, or it refutes or is inconsistent with a position the applicant takes in asserting an argument of patentability or in opposing an argument of unpatentability relied on by the PTO. *See* 37 C.F.R. § 1.56(b) (2008).

7. Under the "reasonable examiner" standard, information is material where there is a substantial likelihood that a "reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent." *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1337 (Fed. Cir. 2008).

8. Rule 56 does not replace or supplant the reasonable examiner standard. Rule 56 was intended by the PTO "to present a clearer and more objective definition of what information the Office considers material to patentability." *See Digital Control Inc. v. Charles Mach. Works*, 437 F.3d 1309, 1314-16 (Fed. Cir. 2006) (citing Duty of Disclosure, 57 Fed. Reg. 2021, 2024 (Jan. 17, 1992).

9. Information is *never* considered material for purposes of inequitable conduct if it is "merely cumulative to, or less relevant than, information already considered by the examiner." *Larson Mfg. v. Aluminart Prods.*, 559 F.3d 1317, 1327 (Fed. Cir. 2009); *Digital Control*, 437 F.3d at 1319 (same); *Eisai Co. v. Dr. Reddy's Labs.*, 533 F.3d 1353, 1361 (Fed. Cir. 2008) ("cumulative evidence is definitionally *not* material evidence").

10. This is true under both PTO Rule 56 and the reasonable examiner standard. *See Tech. Licensing*, 545 F.3d at 1337.

11. If allegedly withheld prior art is later disclosed to the PTO, and the PTO then grants the patent over such art, the grant of the patent can be "strong" evidence that the art is not material. *See Molins PLC v. Textron Inc.*, 48 F.3d 1172, 1179 (Fed. Cir. 1995).

12. In determining unpatentability, the Federal Circuit has long held that "[e]ach claimed invention must be considered as a whole," such that the "restriction of a claimed multistep process to one step constitutes error." *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 1548 (Fed. Cir. 1983).

13. Equally important, "[w]hen weighing whether uncited prior art is more material than that before the examiner . . . the trial court must consider portions of prior art references which teach away from the claimed invention." *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1441 (Fed. Cir. 1991); *W.L. Gore*, 721 F.2d at 1550 (it is error to "disregard[] disclosures in the [prior art] references that diverge from and teach away from the invention at hand").

14. Indeed, the Manual of Patent Examining Procedure ("MPEP") instructs patent examiners that they must consider "both the invention and the prior art references as a whole," and that a "prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention." MPEP § 2141.02 & ¶ VI (8th ed., rev. 7, July 2008) (emphasis in original).

C. Intent to Deceive

15. In addition to proving materiality, Cerner must separately prove by clear and convincing evidence that the Visicu inventors had "a specific intent to deceive the PTO." *Larson Mfg.*, 559 F.3d at 1340.

16. General allegations that Visicu as a corporation was aware of, and withheld, certain prior art is insufficient, for the duty to disclose applies to individuals only, not corporations or organizations. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1329 (Fed. Cir. 2009); *MPEP* § 2001.01 (duty of candor "applies only to individuals, not to organizations").

17. Only a person "substantively involved in the preparation or prosecution" of the Visicu patents can commit inequitable conduct. 37 C.F.R. § 1.56(c)(3). Information in the minds of those not involved in the process is irrelevant.

18. To prove intent, Cerner must meet "a high bar." *Eisai Co.*, 533 F.3d at 1360. Evidence of the inventor's "mistake or negligence, even gross negligence, is not sufficient to support inequitable conduct in patent prosecution." *Astrazeneca Pharm.*, 583 F.3d at 776 (citing *Kingsdown Med. Consultants v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988); *Abbott Labs.*, 544 F.3d at 1353 ("Mistake or negligence, even gross negligence, does not support a ruling of inequitable conduct.").

19. "Given the ease with which a relatively routine act of patent prosecution can be portrayed as intended to mislead or deceive, clear and convincing evidence of conduct sufficient to support an inference of culpable intent is required." *N. Telecom v. Datapoint Corp.*, 908 F.2d 931, 939 (Fed. Cir. 1990) (a "patentee's oversights are easily magnified out of proportion by one accused of infringement") (quotation and citation omitted).

20. "Intent to deceive cannot be inferred from even a high degree of materiality, but must be separately proved by clear and convincing evidence." *Aspex Eyewear, Inc. v. Clariti Eyewear, Inc.*, 605 F.3d 1305, 1316 (Fed. Cir. 2010); *Optium Corp.*, 603 F.3d at 1322 (accused infringer could not "simply argue[] that the 'high materiality' of [a] reference relieved it of the burden to produce any affirmative evidence of intent"); *Eisai Co.*, 533 F.3d at 1362 (even where materiality was high "the lack of deceptive intent rendered stillborn yet another allegation of inequitable conduct").

21. Moreover, "[i]ntent to deceive can not be inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent." *Abbott Labs.*, 544 at 1355 (quotations and citations omitted); *see also Larson Mfg.*, 559 F.3d at 1340 ("nondisclosure, by itself, cannot satisfy the deceptive intent element"). "Extensive precedent continues to reinforce this standard." *Optium Corp.*, 603 F.3d at 1321. And, "[w]hile deceptive intent can be inferred from circumstantial evidence, the circumstantial evidence must still be clear and convincing." *Larson Mfg.*, 559 F.3d at 1340, *see also Star Scientific*, 537 F.3d at 1366 ("inferences drawn from lesser evidence cannot satisfy the deceptive intent requirement").

22. Critically, an inference of deceptive intent "'must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be the *single most reasonable inference* able to be drawn from the evidence to meet the clear and convincing standard.'" *Larson Mfg.*, 559 F.3d at 1340 (quoting *Star Scientific*, 537 F.3d at 1366) (emphasis added). Indeed, the Federal Circuit recently reiterated this key principle in *Purdue Pharma*, 2010 WL 2203101, at *5 (affirming the district court's finding of no inequitable conduct because "intent to deceive is not the single most reasonable inference that can be drawn from the evidence"), and in *Orion IP, LLC v. Hyundai Motor America*, 605 F.3d 967, 979 (Fed. Cir. 2010) (same); *see also Exergen Corp.*, 575 F.3d at 1329 n.5 ("[T]his inference must be the *single most reasonable* inference able to be drawn from the evidence to meet the clear and convincing standard.") (internal quotation omitted).

23. Indeed, "[w]henever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference." *Scanner Techs. Corp. v. ICOS Vision Sys.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008).

24. A "necessary predicate for inferring deceptive intent" is evidence suggesting a "deliberate decision to withhold a known material reference." *Exergen Corp.*, 575 F.3d at 1331.

25. "[A]n accused infringer cannot carry its threshold burden simply by pointing to the absence of a credible good faith explanation" from the patentee. *Leviton Mfg. Co. v. Universal Security Instruments, Inc.*, 606 F.3d 1356, 1363 (Fed. Cir. 2010)

(quoting *Larson Mfg.*, 559 F.3d at 1341). Any such "shift in the burdens is contrary to precedent." *Optium Corp.*, 603 F.3d at 1322.

26. Indeed, "the patentee is not required to offer evidence of good faith unless the accused infringer first meets its burden to prove – by clear and convincing evidence – the threshold level of deceptive intent." *Larson Mfg.*, 559 F.3d at 1341.

27. However, even where a threshold showing of deceptive intent is made, a court must "take into account any evidence of good faith, which militates against a finding of deceptive intent." *Larson Mfg.*, 559 F.3d at 1341.

28. "Even if the nondisclosed information is of 'relatively high materiality,' . . . inequitable conduct cannot be found where '[the patentee] offer[s] a plausible, good faith explanation for why [the nondisclosed information] was not cited to the PTO.'" *Leviton Mfg. Co.*, 606 F.3d at 1362-63 (quoting *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1348 (Fed. Cir. 2005)).

FINDINGS OF FACT

A. Background Facts

29. Dr. Brian Rosenfeld and Dr. Michael Breslow are the named inventors on the patents-insuit, United States Patent No. 6,804,656, and United States Patent No. 7,256,708 ("the '656 patent" and "the '708 patent," respectively). (Plaintiff's Trial Exhibits (hereinafter "PTX") 1 & 5). The '656 and '708 patents are assigned to Visicu. (PTX 1 & 5).

30. Cerner has accused Dr. Breslow and Dr. Rosenfeld of inequitable conduct in the prosecution of the '656 and '708 patents. These allegations are based on theories that the Visicu inventors intentionally withheld from the United States Patent and Trademark Office ("PTO") the following prior art with the intent to deceive the PTO:

- The information contained in Visicu's 510(k) notification to the Federal Food and Drug Administration ("FDA") seeking clearance of the ARGUS Systems's vital signs capture component. *See* 45-97 below.

- The system developed by Dr. M. Michael Shabot and used at Cedars Sinai hospital in Los Angeles, United States Patent No. 5,942,986 to Shabot ("Shabot Patent"), and various publications of Dr. Shabot relating to the Shabot System ("Shabot Publications"). *See* 98-145 below.

- The iMDsoft MetaVision System and the Schoenberg PCT publication. *See* 146-180 below.

31. All of the challenged prior art is found to have been material. However, Cerner has failed to prove by clear and convincing evidence that either Dr. Breslow, Dr. Rosenfeld or any other individual on behalf of Visicu, withheld any reference from the PTO with the specific intent to deceive.

32. All references to the record herein are intended to be exemplary and not exhaustive. The court takes into consideration the testimony, demeanor and credibility of all witnesses herein. The entire record is considered by the court in support of the findings and conclusions set forth in this Order.

1. The Status of Critical Care in 1999

33. In 1999, the common model for managing the care of Intensive Care Unit ("ICU") patients was longstanding and involved the management of patient care primarily by the patients' attending physicians or nurses, who were responsible for making decisions about the management of a patient's care. (Trial Tr. Nov. 19, 2009, at 493:7-21; Trial Tr. Nov. 20, 2009, at 619:5:12 672:7-16; Trial Tr. Nov. 23, 2009, at 825:15:826:10).

34. By 1999, there was a concern regarding shortage of critical care physicians and nurses. A large percentage of ICU patients – approximately 2/3 of all ICU patients – did not receive treatment from trained "intensivists," clinicians specially trained in the care of the critically ill. In addition, ICUs were concerned with quality control issues, including mortality rates and a need for improved communication or medical information. (Trial Tr. Nov. 19, 2010, at 466:18-467:6; 469:11-470:1; 471:17-472:4; 494:13-21; 496:6-467:11; Trial Tr. Nov. 20, 2009, at 578 9-15; 579:23580:1; 591:25-592:7; Trial Tr., Nov. 23, 2009, at 831:13-24).

35. To solve this problem, the critical care establishment tried various methods to address these concerns including expanding hospital ICUs to provide more beds, increasing the number of new intensivists being trained, working to retain those intensivists already in the field, training more lower-level healthcare providers to increase the number of medical professionals available on the ICU floor, and the application of electronic technology. (Trial Tr., Nov. 19, 2010, at 470:6-12; 477:12-478:9; Trial Tr., Nov. 20, 2009, at 580:1013; 581:18-21; 583:23-585:23; Trial Tr., Nov. 23, 2009, 827:20-828:4; Defendant's Trial Exhibits (hereinafter "DTX") 450, 451).

36. In order to facilitate the longstanding model in which each physician would make care decisions for his or her own patients, hospitals instituted systems directed at facilitating transmission of patient data to the individual caregiver, resulting in a proliferation of pagers as well as systems like the Shabot System (discussed *infra* 99-147), which facilitated automatically sending pages and alerts to attending

physicians. (Trial Tr., Nov. 19, 2010, at 470:13-17; 593:18-594:20; 596:15-18; Trial Tr. Nov. 23, 2009, at 826:11-18; 744:13-745:1).

2. The Visicu Invention

37. Dr. Rosenfeld and Dr. Breslow worked as critical care physicians (otherwise known as "intensivists") at Johns Hopkins University in Baltimore, Maryland, where they were on the faculty of the Department of Anesthesia and Critical Care Medicine and attending physicians in the intensive care unit. (Trial Tr. Nov. 19, 2009, at 490:12-20, 491:16492:16; Trial Tr., July 28, 2010, at 243:8-24).

38. Recognizing the problems identified above, Drs. Breslow and Rosenfeld were among those seeking a solution to the shortage of trained intensivists and the issues with quality control in the ICU. Rather than increase the number of doctors and nurses at the bedside and/or increase the information the doctors received, they sought to employ technology to support a model of remote ICU care in which a smaller number of intensivists at a remote site could be leveraged to simultaneously care for a large number of patients in multiple geographically dispersed ICUs. (Trial Tr., Nov. 19, 2009, at 501:21-504:5; Trial Tr., July 28, 2010, at 374:1-18; *see also* Trial Tr., Nov. 23, 2009, at 744:13-745:10).

39. As a part of these efforts, in July 1998, Dr. Rosenfeld and Dr. Breslow co-founded a company called IC-USA. (Trial Tr., Nov. 19, 2009, at 503:6-8). IC-USA later changed its name to Visicu. (Trial Tr., Nov. 19, 2009, at 503:6-8).

40. Visicu was formed by Dr. Breslow and Dr. Rosenfeld to explore the concept that critical care physicians need not be physically present in the ICU, but instead could be remotely leveraged in a number of ICUs simultaneously through the use of technology. (Trial Tr., Nov. 19, 2009, at 501:21-504:5).

41. In November 1999, Dr. Rosenfeld and Dr. Breslow submitted United States Patent Application No. 09/443.072 ("'072 application"). (PTX 1 & 2B ('656 patent and file history)).

42. On October 12, 2004, the United States Patent Office ("PTO") issued United States Patent No. 6,804,656 ("'656 patent"), titled "System and Method for Providing Continuous, Expert Network Critical Care Services from a Remote Location(s)," resulting from the '072 application. (PTX 1). Since that time, the '656 patent was amended pursuant to two PTO reexaminations. (PTX 3B & 4B).

43. In September 2004, Dr. Rosenfeld and Dr. Breslow submitted United States Patent Application No. 10/946.548 ("'548 application'). (PTX 5 & 6B ('708 patent and file history)).

44. On August 14, 2007, the PTO issued United States Patent No. 7,256,708 ("'708 patent"), titled "Telecommunications Network for Remote Patient Monitoring," resulting from the '548 application. (PTX 5).

B. Visicu's 510(k) Submissions to the Food and Drug Administration

45. In the Spring of 2000, Visicu submitted to the FDA a section 510(k) premarket notification ("Visicu 510(k)") for IC-USA's "ARGUS" System. (DTX 814).

46. Cerner alleges that Visicu committed inequitable conduct by failing to disclose certain information contained in Visicu's Spring 2000 510(k) notification to the FDA related to the ARGUS System. In support of its allegations, Cerner offered the opinion of Dr. Charles Safran, who opined that certain information in the Visicu 510(k) was material to patentability.

47. The Visicu 510(k) contains charts that compare components of the ARGUS System to components in the prior art. (DTX 814 at VIS0457758-68). Cerner alleges that the Visicu inventors should have disclosed those charts to the PTO.

1. The FDA Regulatory Terms "Substantial Equivalence" and "Intended Use"

48. In order to gain FDA clearance under the 510(k) process, Visicu was required to show that the vital signs capture component of the ARGUS System, was "substantially equivalent" in its "intended use" to a predicate device, *i.e.*, a device already proven safe and effective for the same intended use. An FDA finding that a device is "substantially equivalent" to an existing device is not equivalent to a finding that the predicate device is material to patentability for purposes of inequitable conduct. *Cf., Arthrocare Corp. v. Smith & Nephew, Inc.*, 310 F. Supp. 2d 638, 668 (D. Del. 2004); *Johns Hopkins Univ. v. Datascope Corp.*, 543 F.3d 1342, 1349 n.3 (Fed. Cir. 2008).

49. The purpose of the FDA regulation is to ensure that medical devices work in a safe and effective manner for their specified intended use. (Trial Tr., July 29, 2010, 420:1118).

50. A 510(k) notification is a regulatory pathway for Class II medical devices. In the 510(k) process, a company submits a notification to FDA to demonstrate that a new device to be marketed in the United States is at least as safe and effective – that is, "substantially equivalent" – for a specified intended use as a so-called 'predicate device," which is a device already approved for the same specific use. (Trial Tr., July 29, 2010, at 421:5422:12).

51. The term "substantial equivalence" in the context of a 510(k) has a very specific regulatory definition. For the FDA, substantial equivalence is defined as being able

to demonstrate that a new device is at least as safe and effective as a predicate device for a specified intended use. (Trial Tr., July 29, 2010, at 421:13-24).

52. A determination of "substantial equivalence" cannot be made absent an understanding of the intended use statement included in a 510(k). In fact, when a new device is cleared via the 510(k) process, it will only be cleared for the specific intended use identified by the sponsor. (Trial Tr., July 29, 2010, at 422:13-22).

53. Once the intended use of a new device is determined, that use is compared to the "intended use" of a "predicate device." (Trial Tr., July 29, 2010, at 431:14-432:22).

54. An FDA decision that a device is "substantially equivalent" to a predicate device does not mean that the devices are the same. Rather, it means that they have a similar category of technological characteristics *for the specific intended use only*. (Trial Tr., July 29, 2010, 438:1-440:12; 442:16-18).

55. In its 510(k) notification, Visicu identified the intended use of the ARGUS System as follows: "The IC-USA ARGUS System is intended for use in data collection, storage and clinical information management with independent bedside devices, and ancillary systems that are connected either directly or through networks. The IC-USA ARGUS System is intended to provide patient information at the point of care location and at a remote supplementary care location through wide area networking technology and dedicated phone lines." (DTX 814 at VIS0457766).

2. The Decision to Seek 510(k) Clearance and the Patterson Consulting Group

56. At the outset, Visicu was unsure whether any component of the ARGUS System was subject to FDA regulation at all. (Trial Tr., July 28, 2010, at 383:3-8). Therefore, Visicu hired a consultant – the Patterson Consulting Group – to help them understand whether the ARGUS System fell within FDA's purview and, if it did, to assist in seeking clearance. (Trial Tr., July 29, 2010, at 383:3-11; Cerner Spurrier IC Dep. at 42:13-18).

57. Two Patterson Consulting Group employees worked on the Visicu 510(k): Carol White and Carol Patterson. (Cerner Spurrier IC Dep. at 44:4-19). Only two Visicu representatives, Dr. Breslow and Ms. Nanette Spurrier, participated in the 510(k) process alongside the Patterson Consulting Group. (Cerner Spurrier IC Dep. at 49:1-14).

58. Dr. Rosenfeld had no involvement in Visicu's 510(k) submissions. (Trial Tr., July 28, 2010, at 303:12-14).

59. The Patterson Consulting Group took the lead on the Visicu 510(k), and instructed Ms. Spurrier on how to put the notification together. (Cerner Spurrier IC Dep. at 46:1747:12). The Patterson Consulting Group likewise took the lead on preparing much of the written notification, including the device comparison charts. (Cerner Spurrier IC Dep. at 210:12-213:13). Dr. Breslow was significantly involved in the process.

60. The Patterson Consulting Group concluded that the ARGUS System had numerous components and features which were not subject to regulation by FDA or were subject to a lower level of regulation (Class I) that did not require a 510(k) submission. (Trial Tr., July 29, 2010, at 426:2-23: DTX 304).

61. An "internal regulatory review draft" prepared by the Patterson Consulting Group describes its conclusion that some ARGUS components did not require clearance and would likely be classified as "Class I, 510(k) exempt," "not specifically classified by FDA," or "not regulated as medical devices." (DTX 304 at VIS0081538).

62. The Patterson Consulting Group concluded that only the "vital sign capture" component of the ARGUS System, which was used to capture and transmit physiologic patient data from bedside devices over a network, would be classified and regulated as a Class II device under the product code "MSX (System Network and Communication, Physiological Monitors): and would necessitate a 510(k) notification." (Trial Tr., July 29, 2010, at 424:3-426:23; DTX 304 at VIS0081538). Nonetheless, the 510(k) included descriptions of numerous components of the VitalCom System, and comparisons between numerous components of the VitalCom System and the ARGUS System including, *inter alia*, access to multiple remote ICUs, real-time data review, retrospective data review, and system alarms. [DTX 814 at VIS0457767]. Additionally, the Visicu 510(k) included numerous VitalCom System documents describing material features of the VitalCom System, which Dr. Breslow admitted he reviewed and was aware of. [Jul. 28 Tr. at 382:22-385:8; Spurrier Dep. at 49:1-4, 63:21-72:11; PX 20; PX 133]. In addition, the 510(k) itself indicates that the entire ARGUS System was at issue in the FDA 510(k) process, that Visicu was seeking FDA approval "to market and distribute the ARGUS System" (not merely the vital signs capture component of the ARGUS System), and that the ARGUS System includes far more than the vital signs capture component. Moreover, the ARGUS System also includes an interactive patient care videoconferencing system, a film scanner, PC work stations, a tool suite, a decision support system, local and wide area networks, and security features. [PX 133 at VIS571985-76, VIS572016].

63. The Patterson Consulting Group's internal regulatory review draft notes that "the vital signs capture component of the system may be classified by FDA as a Class II device under [the product code] 74 MSX," thus requiring 510(k) notification, and that "other manufacturer's premarket notifications were approved under the MSX

classification which sounded similar to the vital signs capture capabilities of the [ARGUS] System." (DTX 304 at VIS0081538-39; Trial Tr., July 29, 2010, at 424:21-425:2).

64. The FDA ultimately classified the ARGUS System as a Class II device under product code MSX. (Trial Tr., July 29, 2010, at 425:22-426:1).

65. The vital signs capture component of the ARGUS System comprises approximately only 3% of the data that is captured and displayed in the Visicu System. (Trial Tr., July 28, 2010, 393:18-22).

3. Cerner Has Failed to Prove That Visicu Intended to Deceive the PTO By Not Disclosing the Information about the VitalCom System in Visicu's 510(k)

66. Once the Patterson Consulting Group determined that the ARGUS System would likely necessitate a 510(k) notification, Dr. Breslow worked with the Patterson Group's employees, including its founder Carol Patterson, on preparing the notification. (Trial Tr., July 28, 2010, at 382:22-383:2).

67. Ms. Patterson's role involved, among other things, identifying predicate devices to which the ARGUS System's vital signs capture component was "substantially equivalent" for its specified "intended use." (Cerner Spurrier IC Dep. at 51:12-52:11; 53:20-54:1; DTX 304 at VIS00881548). In addition, the Patterson Consulting Group took the lead on submissions to, and communications with, the FDA. (Cerner Spurrier IC Dep. at 58:1759:4). Dr. Breslow assisted.

68. Logs of phone calls from the Patterson Consulting Group to FDA officials reflect discussions concerning "the vital signs capture component of the system whereby information from other manufacturer's bedside monitors would be relayed not only to the ICU nurse's station but also to a central telemedicine center." (DTX 304 at VIS0081548).

69. Dr. Breslow provided the consultant with information about the ARGUS System to prepare the 510(k) notification and reviewed the notification for completeness and accuracy before its submission to the FDA. (Trial Tr., July 28, 2010, at 382:22-384:11).

70. For the 510(k) submission, Visicu and the Patterson Consulting Group identified to the FDA in the 510(k) notification two predicate devices, the VitalCom System and CareVue 9000/Device Link System. (DTX 814 at VIS0457760-68).

71. In conversations between Carol Patterson and the FDA, the FDA had identified the VitalCom Systems as a device that had been cleared via the 510(k) process and

appeared to have features similar to that of the ARGUS System. Based on this identification of similar features, the Patterson Consulting Group recommended to Visicu that VitalCom be identified as a predicate device. (Trial Tr., July 29, 2010, 426:2-429:4; DTX 304 at VIS0081548).

72. In the 510(k), Visicu identified the intended use of the VitalCom Networked Monitoring System predicate device as being "indicated for those patients who are connected via ambulatory ECG transmitters, bedside monitors or . . . ventilators. The VitalCom Central Monitoring Station (VCOM) is to be installed at the point of care locations that have the capability of installing hardware paths to a VCOM from rooms or areas where bedside monitors or . . . ventilators operate. If employing wide area networking technology, the communications between the VCOM, at the point of care location, and the IRVS/RVS, at the supplementary care location, is facilitated by dedicated telephone lines and commercially available interface hardware." (DTX 814 at VIS0457766).

73. In its 510(k) notification, Visicu identified the intended use of the ARGUS System as follows: "The IC-USA ARGUS System is intended for use in data collection, storage and clinical information management with independent beside devices, and ancillary systems that are connected either directly or through networks. The IC-USA ARGUS System is intended to provide patient information at the point of care location and at a remote supplementary care location through wide area networking technology and dedicated phone lines." (DTX 814 at VIS0457766).

74. The VitalCom intended use statement (and Visicu's comparison to VitalCom for that intended use) relates to the ability of VitalCom to capture vital signs information from devices such as bedside monitors and ventilators, and transmit that information accurately over a network. (Trial Tr., July 29, 2010, at 433:11-21).

75. The FDA had questions regarding a variety of issues including the ARGUS Systems vital signs capture component. (Trial Tr., July 29, 2010, at 435:4-23; DTX 816 at VIS0572543).

76. Nearly every criteria used to compare the ARGUS System to the VitalCom and CareVue Systems in the Visicu 510(k) relates to vital signs capture. (Trial Tr., July 28, 2010, at 387:5-388:4; 389-21-390:2; 393:10-17). This is only a small subset of the ARGUS System – only approximately 3% of the data captured and displayed by the system relates to vital signs capture technology. (Trial Tr., July 28, 2010, at 393:18-22). (Trial Tr., July 27, 2010, at 175:12-176:3; 176:20-177:5; 177:9-11).

77. Thus, a finding of "substantial equivalence" of the ARGUS System and the predicate devices is not of itself a finding of materiality. Rather, it demonstrates that a component of the ARGUS System that was the subject of the 510(k) charts is "substantially equivalent" to similar components in the predicate devices for their

specified intended use of capturing and transmitting vital signs data over networks. *See* 48-76, above.

78. Dr. Breslow understood that the point of a 510(k) is to establish that a device will not cause patient harm. It was his understanding that only a very small component of the ARGUS System fell under the purview and was of potential concern to the FDA, namely, the processing of patient vital sign data. The processing of vital sign data comprised only approximately 3% of what the ARGUS System did. Thus, it was his understanding that a device "substantially equivalent" for FDA purposes "had absolutely nothing to do with our system [being] globally the same as any other system. It was solely related to the way in which vital sign data were received, manipulated, and displayed. That was my understanding." (Trial Tr., July 28, 2010, at 392:10-393:9).

79. The Patterson Consulting Group informed Dr. Breslow that the only thing of interest to the FDA with regard to the ARGUS System was that it received vital sign data from the bedside monitors, computed it into means and to medians, and displayed it graphically. Therefore, Visicu and the Patterson Consulting Group focused on other devices only with respect to how they managed vital sign information in order to show that it could be used safely in a patient care environment. (Trial Tr., July 28, 2010, at 393:20-393:6).

80. Thus, with respect to VitalCom, Dr. Breslow believed the only relevant similarity with the ARGUS System was the manner in which VitalCom captured and used vital signs data. (Trial Tr., July 28, 2010, at 399:20-400:3; 392:10-393:9).

81. It was Dr. Breslow's understanding that the information in the 510(k) did not relate to the Visicu System globally, but solely to the manner in which it captured vital sign data. (Trial Tr., July 28, 2010, at 393:6-9; 399:20-400:3).

82. Dr. Breslow did not provide the PTO with information regarding VitalCom because he believed that the VitalCom System directed the use of technicians to monitor alarms rather than managing ICU patients as was the intent of the Visicu System. (Trial Tr., July 28, 2010, at 396:13-397:22; 398:4-22).

83. Dr. Rosenfeld likewise believed that VitalCom was "dramatically different" from the Visicu System, largely because the VitalCom System was a monitoring system and lacked "intelligence." (Trial Tr., July 28, 2010, at 302:3-17).

84. It was Dr. Breslow's belief that in the VitalCom System, the technician who monitored patient physiologic data made no care decisions or proactive interventions and reviewed only vital sign data. (Trial Tr., July 28, 2010, 398:15-22).

85. Because he believed it was fundamentally different from the Visicu System, it did not occur to Dr. Breslow to submit to the PTO Visicu's 510(k) notifications or the limited information contained in them about the predicate devices and intended use. *See* 79-85 above.

86. Neither Dr. Breslow nor Dr. Rosenfeld intended to deceive the PTO by not submitting information regarding VitalCom, or Visicu's 510(k) to the PTO and they have provided a good faith reason for not disclosing the VitalCom System.

4. Cerner Has Failed to Prove Deceptive Intent with Respect to the CareVue 9000/HP Agilent Device Link System Discussed in Visicu's 510(k)

87. As previously stated, Visicu and The Patterson Consulting Group identified the CareVue 9000/Device Link System as a predicate device in addition to the VitalCom System in the 501(k) submission.

88. The specific "intended use" of the CareVue 9000 System, as stated in the CareVue FDA 510(k) and relied upon by Visicu in its own 510(k), is as follows: "The HP CareVue 9000 is a clinical information system intended for use in data collection, storage, and management with independent bedside devices, and ancillary systems that are connected either directly or through networks. It is indicated for use by health care providers whenever there is a need for generation or a patient record and computation of a drug dosage." (Trial Tr., July 29, 2010, at 431:21-432:15; DTX 814 at VIS0457761).

89. As with the VitalCom System, the intended use statement for the CareVue 9000/Device Link System is consistent with the focus of Visicu's 510(k). (Trial Tr., July 28, 2010, at 432:23433:2).

90. It was Dr. Breslow's understanding that the CareVue 9000/Device Link System used a vital signs capture component similar to the ARGUS System, comprising patient monitors (the source of the vital signs data), software data transmission of the vital signs data from the bedside monitors into the system, equipment interconnection (the network the vital signs data traveled over), real-time and retrospective data review (allowing review of the vital signs data), and particular types of vital signs monitors (e.g., blood pressure, heart rate). (Trial Tr., July 28, 2010, at 387:15-390:2).

91. It was Dr. Breslow's understanding that CareVue 9000/Device Link System was nothing more than an ICU clinical information system ("CIS"), much like the EMTEK System used at Johns Hopkins. (Trial Tr., July 28, 2010, at 390:5-390:8).

92. Dr. Breslow did not disclose the CareVue 9000/Device Link System because he believed it was nothing more than a CIS, which he perceived as a commercially

available, off-the-shelf technology that had been manufactured by a dozen different companies and had been in use for almost a decade. (Trial Tr., July 28, 2010, at 390:13-391:11).

93. Dr. Breslow did not believe that an off-the-shelf CIS was central to the Visicu invention. (Trial Tr., July 28, 2010, at 390:13-22).

94. As understood by Dr. Breslow, the CareVue 9000/Device Link System was intended for use by nurses to complete their charting at the bedside. (Trial Tr., July 28, 2010, at 391:3-11).

95. Dr. Breslow did not believe that the overall CareVue System was similar in its intended use or functionality to the Visicu System. (Trial Tr., July 28, 2010, at 393:10-394:6). Dr. Breslow did not intend to deceive the PTO by not disclosing the CareVue System.

96. Dr. Breslow provided a good faith reason for not disclosing the information in the Visicu 510(k) relating to the CareVue 9000/Device Link System to the PTO.

97. Cerner has failed to show that information in the Visicu 510(k) was withheld from the PTO with the intent to deceive. *See* 45-97, above.

C. The Shabot System

98. Cerner's second inequitable conduct allegation is that Dr. Breslow and Dr. Rosenfeld withheld information regarding a system at Cedars Sinai Medical Center (the Shabot System), including information regarding the system itself, a patent related to the system, and articles describing the system.

1. Background Information Regarding the Shabot System

99. The Shabot System is a prior art system developed by Dr. M. Michael Shabort for use at Cedars Sinai Medical Center in Los Angeles ("Shabot System"). More specifically, Dr. Shabot developed a rules engine that extracted data from a Clinical Information System ("CIS") and applied rules to trigger alerts. (PTX 586, Cerner's Shabot Dep. at 20:16-21:1, 74:5-13).

100. The Shabot System sent the alerts to pagers carried by patients' individual medical providers. (Cerner's IC designation of Shabot Dep. at 20:16-21:1; PTX 105 at CERN03101 ("The authors have developed a clinical alerting system which delivers alerts and reminders to clinicians in real time via a [sic] alphanumeric display pagers."); PTX 129 (abstract) ("page each responsible physician")).

101. The Shabot System used an alerting engine to determine which particular care providers received any individual alert. (PTX 586 (November Shabot Designations) at 85:23-86:3; 88:16-89:3)). The goal was to send the page to as many medical providers as possible in the hope that the alert was received by someone. (*Id.* at 85.12-86:3).

102. The Shabot System was described in published articles, including a 2000 AMIA Article. It was also described in a 1995 AMIA Article. (PTX 105 at CERN003101-CERN003105) ("2000 AMIA Article"), & PTX 18 at CERN003097-100 ("1995 AMIA Article:)).

103. In addition, on August 24, 1999, Dr. Shabot received a patent, United States Patent No. 5,942,986 ("Shabot Patent"), a "System and Method for Automatic Critical Event Notification," which claims a system providing "critical event notifications" to "an alphanumeric pager" carried by the physician(s)" responsible for the patient." (PTX 129 at CERN003064-87 ('986 Abstract)).

2. The Shabot System was disclosed by Visicu in the '656 Reexamination and the '708 Prosecution

104. During the original '708 prosecution and the first '656 reexamination, Visicu disclosed to the PTO numerous pieces of art related to the Shabot System, none of which resulted in any office action or claim rejection. In total, VISICU disclosed sixteen Shabot references to the PTO – the Shabot Patent and fifteen publications, including both the 1995 and 2000 AMIA Articles. (PTX 3B at CERN393958-394038 (ref. nos. 1, 29, 30, 40, 74, 123, 135-37, 145-50), PTX 3B at CERN393816, PTX 6B at CERN396969-6986 (ref. nos. 1, 29, 30, 40, 74, 123, 135-37, 145-50), & PTX 6B at CERN396940).

a. Disclosure of the Shabot System in the First '656 Reexamination

105. Visicu disclosed the Shabot Patent to the PTO in the first '656 reexamination in a June 8, 2005 Information Disclosure Statement ("IDS"). (PTX 3B (CERN393816)).

106. In describing the Shabot Patent, Visicu took the position that, much like other art before the examiner, Shabot disclosed a "critical event notification system" whereby alerts or "critical event notifications" were sent to individual physician pagers. However, in the Shabot Patent, the applicant specifically noted that "critical event[s]" occurred when "one or more parameters f[e]ll outside the pre-determined values, individually or simultaneously." The application further noted that in the Shabot Patent, decisions regarding patient care remained in the hands of the paged physician, and was conditioned on receipt of an alert by that physician. (PTX 3B at CERN393816-20).

107. The Shabot Patent was considered by the Examiner in the first ‘656 reexamination on September 20, 2005. No claims were rejected based on the Shabot Patent. (PTX 3B (CERN393882)).

108. After the Shabot Patent was disclosed to and reviewed by the PTO, the applicants disclosed both the 1995 and 2000 AMIA Articles in the first ‘656 reexamination in a Dec. 21, 2005 IDS. (PTX 3B (CERN393980, Ref. 40; CERN394035, Ref. 147)).

109. The articles were considered by the Examiner on February 22, 2006, and no claims were rejected based on either article. PTX 3B (CERN396611; CERN396622).

110. Visicu’s claims were never rejected on the basis of the Shabot art. (*See generally* PTX 3B (First Reexamination file history); Trial Tr., July 27, 2010, at 131:5-15).

b. Shabot Art Was Disclosed to the PTO During the Original ‘708 Patent Prosecution.

111. In the original ‘708 prosecution, the Visicu applicants first disclosed the Shabot System via the Shabot Patent in a March 8, 2005 IDS. (PTX 6B at CERN396939-3940).

112. The Shabot Patent was considered by the Examiner in the ‘708 prosecution on Dec. 21, 2006. (PTX 6B at CERN399428).

113. Similarly the applicants disclosed the 1995 and 2000 AMIA Articles to the PTO in the ‘708 prosecution in a February 23, 2006 IDS, providing copies of the articles to the examiner PTX 6B at CERN396969-6970; CERN396975, Ref. 40; CERN396986, Ref. 147).

114. The articles were considered by the ‘708 Examiner on Dec. 21, 2006. (PTX 6B at CERN399438 & CERN399449).

115. Because the Shabot Patent and both the 1995 and 2000 AMIA Articles were disclosed in the original ‘708 prosecution, there can be no inequitable conduct with respect to the ‘708 patent based on the Shabot art, without reference to the prosecution of the ‘656 patent. *Agfa Corp. v. Creo Prods.*, 451 F.3d 1366, 1379 (Fed. Cir. 2006); *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1230 (Fed. Cir. 2007) (“inequitable conduct with respect to one or more patents in a family can infect related applications.”); *Fox Indus., Inc. v. Structural Pres. Sys., Inc.*, 922 F.2d 801, 803-804 (Fed. Cir. 1990) (“A breach of the duty of candor early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application.”). *See, e.g., Molins PLC v. Textron*, 48 F.3d 1172, 1185 (Fed. Cir. 1995) (reference not “withheld” when it was before the examiner).

116. Nor can inequitable conduct be found based on any statement by the applicants that the Shabot art was "cumulative." When art is before the examiner, "an applicant is free to advocate its interpretation of its claims and the teachings of prior art." *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1379 (Fed. Cir. 2008).

117. Dr. Breslow has no memory of looking at the 1995 AMIA Article or of obtaining any of the other references in the 2000 AMIA Article. (Trial Tr., July 28, 2010, at 362:11363:8).

118. Dr. Rosenfeld has never seen the Shabot System, and has never read the Shabot Patent. (Trial Tr., July 29, 2010, at 298:6-7, 14-17).

3. Dr. Breslow's Knowledge of the Shabot System

119. After the filing of the '072 patent application in 1999, the inventors and Visicu representatives began actual work on writing the code for an implementing the complete series of specific alerts they wanted to use in the commercially available Visicu System. (Trial Tr., July 28, 2010, at 347:13-16). These specific alerts and their clinical values are not claimed in the '656 patent. (*See* PTX 1 (all claims); PTX 5 (all claims)).

120. As part of this effort, in March 2000, Dr. Breslow contacted Dr. Shabot to see if Dr. Shabot might consult with Visicu in developing specific rules or "smart alarms" for the Visicu rules engine. (Trial Tr., July 28, 2010, at 339:15-340:3; 341:6-13 & PTX 128 at CERN003029-CERN003030). More specifically, it was Dr. Breslow's understanding that Dr. Shabot had experience using alerts in the ICU and Dr. Breslow hoped he might be able to facilitate the development of Visicu's own specific alerts. (Trial Tr., July 28, 2010, at 340:1-3).

121. Dr. Breslow hoped to gain clinical insight from Dr. Shabot regarding the nature of specific alerts that he had found useful in patient care. (Trial Tr., July 28, 2010, at 352:14-16). He hoped Dr. Shabot might assist in advising Visicu on the specific clinical level or threshold that should be used to trigger an alert. (Trial Tr., July 28, 2010, at 352:19-353:4). He believed Dr. Shabot might be aware of which particular values gave appropriate sensitivity, from a clinical perspective, for use in an alert. (Trial Tr., July 28, 2010, at 368:3-10).

122. After a phone conversation, Dr. Breslow and Dr. Shabot exchanged e-mails, arranging to meet in Los Angeles on the afternoon of April 18 at Cedars Sinai with dinner to follow. (DTX 128 at CERN002983-94).

123. Dr. Breslow already planned to be on the West Coast on business on April 18, 2000, and therefore arranged to include a stop at Cedars Sinai as a part of the trip. (Trial

Tr., July 28, 2010, at 341:6-13; Visicu's IC Designations of Doerfler Dep. at 188:1-8).

124. In the late afternoon of April 18, 2000, Dr. Breslow visited Dr. Shabot along with a second Visicu employee, Dr. Martin Doerfler. (Visicu's IC Designations of Shabot Dep. at 21:15-22:17).

125. Dr. Breslow and Dr. Doerfler spent approximately 20 minutes in the ICU with Dr. Shabot. (Visicu's IC Designations of Shabot Dep. at 27:16-28:23; 30:15-24; Trial Tr., July 28, 2010, at 356:3-8).

126. Dr. Shabot testified that, although he could not recall many details, he would have shown Dr. Breslow and Dr. Doerfler his own pager to illustrate the types of alerts sent and he would have shown the doctors the underlying CIS display units in the ICU. (Visicu's IC Designations of Shabot Dep. at 27:19-28:23; 34:12-35:20).

127. In addition, he would have shared with Dr. Breslow how the rules engine worked, the data it received, and the types of alerts sent to particular caregivers, e.g., which alerts went to nurses and which to the pharmacy. (Visicu's IC Designations of Shabot Dep. at 27:19-28:23, 35:8-20).

128. Dr. Breslow recalls walking into the ICU, being shown Cedar Sinai's CIS (which was a commercially available CareVue System), seeing a couple of large ICU rooms that included patient monitors and equipment, and seeing Dr. Shabot's "beeper," in which he received an alert regarding potassium values. (Trial Tr., July 28, 2010, at 356:1-24).

129. After the meeting, Dr. Breslow and Dr. Shabot exchanged a series of emails, and, on May 1, 2000, Dr. Breslow emailed Dr. Shabot detailed technical information regarding the Visicu System. (PTX 127 at CERN002993).

130. Dr. Breslow offered Dr. Shabot a consulting position with Visicu, a position that Dr. Shabot eventually declined in September 2000. (Trial Tr., July 28, 2010, at 348:4-7; DTX 130 at CERN003029, CERN003044). Visicu had retained between 20 and 40 physician consultants to assist in developing various aspects of the commercial Visicu System. (Trial Tr., July 28, 2010, at 349:18-22; 355:7-14).

131. Prior to the 2000 meeting at Cedars Sinai, Dr. Shabot sent Dr. Breslow an as of yet unpublished article regarding the Shabot System. (Trial Tr., July 28, 2010, at 344:16-345:1; PTX 17).

132. Said unpublished article, *Wireless Clinical Alerts for Physiologic, Laboratory and Medication Data*, was later published in 2000 in the Proceedings of the AMIA Annual Symposium. (PTX 105). It was published after the filing of the '072 Application.

133. The 2000 AMIA Article is directed to "a clinical alerting system which delivers alerts and reminders to clinicians in real time via a [sic] alphanumeric display pagers." (PTX 17 at VIS0083636).

134. The five-page article refers heavily to the use of pagers. (Trial Tr., July 27, 2010, at 1217:7-11; PTX 17).

135. Dr. Breslow later cited the 2000 AMIA Article in a 2004 white paper of his own for the proposition that "there have been only scattered reports of the use of real-time alerts to facilitate timely interventions in critically ill patients." (PTX 617 at VIS0371952). This reflects that Dr. Breslow was not attempting to conceal the article from the PTO.

4. Dr. Breslow Did Not Intend to Deceive the PTO with Respect to the Shabot System

136. Dr. Breslow had a good faith reason for not disclosing information regarding the Shabot Paging System to the PTO. *See* 138-147, below.

137. Based on the meeting at Cedars-Sinai, Dr. Breslow believed that the intended use of Dr. Shabot's system was "diametrically opposite" and "absolutely antithetical" to the intended use of the Visicu System. (Trial Tr., July 28, 2010, at 366:2-7).

138. In Dr. Breslow's view: "[Dr. Shabot's] model was – he was an onsite physician. He realized he couldn't be in the intensive care unit 24 hours a day 7 days a week and, therefore, when something went plunk in the night if he could have somehow have [sic] a pager go off and tell him that he better return his attention back to the ICU, whether he was on the golf course, at home with his family, or asleep, that was his intended use of these alerts. He couldn't be there all the time and, therefore, when something really went wrong, he needed to be notified of that." (Trial Tr., July 28, 2010, at 366:11-19).

139. Dr. Breslow believed the Shabot System was dependent on the old paradigm where the onsite doctor is the only provider of care." (Trial Tr., July 28, 2010, at 373: 19-25).

140. This was vastly different – indeed, "diametrically opposed" – to Dr. Breslow's perception of his own invention. (Trial Tr., July 28, 2010, at 366:2-7). In Dr. Breslow's view, the Visicu System "was envisioned entirely different. [Visicu] wanted to make sure that all of these high acuity patients were being watched continuously by the equivalent of a Dr. Shabot or a Dr. Breslow or a Dr. Rosenfeld 24 hours a day 7 days a week so that before things went awry, they could be identified, countermeasures could be instituted, and complications could be avoided." (Trial Tr., July 28, 2010, at 366:20-367:1).

141. Dr. Breslow did not believe that Dr. Shabot's idea could "fix the problems in terms of quality control and outcomes in the [ICU]." While Dr. Breslow believed that "some of his ideas could be harnessed and put within the [Visicu] system to make the [Visicu] system even more robust than it already was," in his mind he was "philosophically 100 percent opposed to the idea that one intensivist could cover patients from their home." (Trial Tr., July 28, 2010, at 367:2-9).

142. Dr. Breslow felt that "to use Dr. Shabot's system to fix the problems in critical care that [the inventors] thought were really pressing, you would have to create ten times as many intensivists as existed at that point in time, because Dr. Shabot was not covering more patients than any other intensivist. He was just trying to make sure that even when he wasn't there, if something really bad happened, he would know about it." (Trial Tr., July 28, 2010, at 367:10-19; 373:19-25).

143. Dr. Breslow viewed the Visicu model as entirely distinct, in that Visicu sought to "create a system that let you network patients form multiple ICUs providing information to the clinicians in a way that they could work very efficiently and reliably." (Trial Tr., July 28, 2010, at 374:9-12).

144. To illustrate, while Dr. Shabot cared for a 20-bed surgical ICU, the standard implementation of the Visicu invention uses one physician for more than a hundred patients. (Trial Tr., July 28, 2010, at 374:12-16). Dr. Breslow viewed this shift in operating model as "absolutely opposite to anything that Dr. Shabot had envisioned." (Trial Tr., July 28, 2010, at 374:16-18).

145. Dr. Breslow did not intend to deceive the PTO by not submitting the 2000 Shabot AMIA article describing Dr. Shabot's System. *Larson Mfg.*, 559 F.3d at 1340 (quoting *Star Scientific*, 537 F.3d at 1366) (emphasis added); *Scanner Techs.*, 528 F.3d at 1376 ("[W]henever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference."). There is no finding of deceptive intent because Dr. Breslow has offered "a plausible, good faith explanation for why [the disclosed information] was not cited to the PTO." *Leviton Mfg. Co.*, 606 F.3d at 1363 (quoting *Warner-Lambert*, 418 F.3d at 1348).

D. <u>The Schoenberg MetaVision System</u>

146. Cerner's third inequitable conduct allegation is that Dr. Breslow and Dr. Rosenfeld withheld information regarding the iMDsoft MetaVision System and a related Schoenberg PCT Publication WO98/29790 ("Schoenberg PCT publication") ("PTX 212) from the PTO with the intent to deceive.

1. Background of iMDsoft

147. Dr. Ido Schoenberg is a founder of iMDsoft and the current chairman of its Scientific Advisory Board. (Visicu's IC Designations of Schoenberg Dep. at 10:24-12:17). He is also a named inventor on the Schoenberg PCT Publication. (PTX 212).

148. Dr. Schoenberg's wife, Phyllis Gotlib, is iMDsoft's CEO. (Visicu's IC Designations of Schoenberg Dep. at 11:7-14; 183:13-18). She too is a named inventor on the Schoenberg PCT Publication (PTX 212).

149. iMDsoft has sought to invalidate Visicu's patents in the PTO, and Visicu sued iMDsoft in 2007 related to a product iMDsoft installed at Lehigh Valley Hospital. (Visicu's IC Designations of Schoenberg Dep. at 173:22-176:19; 194:4-14; Trial Tr., July 28, 2010, at 267:9-17).

2. Cerner's MetaVision Allegations

150. Cerner's allegations stem from a meeting that took place while Drs. Breslow and Rosenfeld were still working as intensivists at Johns Hopkins in November 1997 ("November 1997 meeting"). This meeting which occurred on November 11, 1997, included iMDsoft's Dr. Schoenberg and Phyllis Gotlib, and at least Dr. Rosenfeld, Dr. Breslow and a colleague of theirs from Johns Hopkins, Dr. Todd Dorman, and possibly a second colleague, Dr. James Fackler. (Visicu's IC designation of Schoenberg Dep. at 243:20-244:24; Trial Tr., July 28, 2010, at 256:24-257:20; 261:3-6; 329:14-20; 332:20-333:15; & Visicu's IC designation of Dorman Dep. at 100:9-19).

151. While iMDsoft held additional meetings with various Johns Hopkins staff, neither Dr. Breslow nor Dr. Rosenfeld was present at any meeting other than the November 1997 meeting. (Trial Tr., July 28, 2010, at 262:23-25; 339:1-3; 108:2-13).

152. Rather, these other meetings were with Dr. Dorman, Dr. Fackler and others. (Trial Tr., July 28, 2010, at 262:23-25; Visicu's IC designation of Dorman Dep. at 81:78; 82:15-83:1; 90-4-91:5; 98:19-100:4; 108:2-16; 121:8-123:15; 125:5-126:13; 129:5131:16).

153. In addition to meeting separately with Dr. Dorman, iMDsoft later received a letter from and exchanged e-mail correspondence with Dr. Dorman. Ths Visicu inventors had no association with these communications. (Trial Tr., July 28, 2010, at 262:2-263:17; Visicu's IC designation of Dorman Dep. at 129:5-131:16; PTX 56; PTX 190). The emails and letters were not sent to or from Drs. Breslow or Rosenfeld and were never seen by either inventor prior to this litigation. (*See, e.g.*, Trial Tr., July 28, 2010, at 261:7-263:17; PTX 190 (e-mails); PTX 191 (letter).

154. Cerner's expert, Dr. Safran, testified that the MetaVision System was material, in part, because it used a multi-parameter rules engine in the context of remote access. (Trial Tr., July 27, 2010, at 179:19-23).

155. Dr. Safran relies, in part, on the MetaVision System installed at Massachusetts General Hospital ("MGH") in 1997 to conclude that MetaVision circa 1997 included a multi-parameter rules engine in the context of remote access. (Trial Tr., July 27, 2010, at 178:19-24).

156. The court does not find that anyone involved in the Visicu patent prosecutions had knowledge of the MGH System.

157. Cerner relies, in part, on the November 1997 meeting at Johns Hopkins attended by Drs. Rosenfeld and Breslow to prove knowledge of the materiality of MetaVision.

158. At the November 1997 meeting, Dr. Schoenberg and Phyllis Gotlib provided attendees with a limited demonstration on a laptop of his clinical information system. (Cerner's IC designation of Schoenberg Dep. at 109:8-22 & Cerner's IC designation of Dorman Dep. at 84:13-85:21; Trial Tr., July 28, 2010, at 258:23-259:1; 333:16-18).

159. This limited demonstration included one screen shot of the iMDsoft System on a small laptop. (Trial Tr., July 28, 2010, at 258:23-259:1).

160. Dr. Schoenberg demonstrated some of the system's features and mentioned its use at a hospital in the Northeast. (Trial Tr., July 28, 2010, at 333:17-22).

161. Neither Dr. Breslow nor Dr. Rosenfeld has any recollection of iMDsoft demonstrating a system with a rules engine at the November 1997 meeting. (Trial Tr., July 28, 2010, at 259:15-260:7 (Dr. Rosenfeld); 338:3-339:11 (Dr. Breslow)).

162. Neither Dr. Breslow nor Dr. Rosenfeld has any recollection of iMDsoft demonstrating any ICU remote monitoring capabilities at the meeting. (Trial Tr., July 28, 2010, at 259:15-17 (Dr. Rosenfeld); 338:19-25 (Dr. Breslow)).

163. Dr. Breslow and Dr. Rosenfeld were not aware of the materiality of the iMDsoft System based on the November 1997 meeting. *See* 150-163 above.

a. Dr. Dorman's Testimony Corroborates the Inventors' Testimony

164. Dr. Todd Dorman is the former Director of Critical Care Information Systems at Johns Hopkins. (Visicu's IC designation of Dorman Dep. at 12-15:5).

165. He is "an uninterested party." (Cerner's Suggestions in Opp'n to Visicu's Mot. for S.J. of No Inequitable Conduct, Dkt.314, at 12).

166. Dr. Dorman testified as follows regarding multi-parameter rules:

Q: "Do you recall discussing computerized rules at that meeting?
A: "No."
Q: "Do you recall discussing Smart Alarms or Smart Monitors at that meeting?"
A: "No. I do not."

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Q: "Do you know if iMDsoft had Smart Alarms or Smart Monitors?"
A: "I don't believe anybody did at the time."
Q: "But, did iMDsoft talk about work they were doing on Smart Alarms or Smart Monitors?"
A: "Not that I recall."

(Visicu's IC designation of Dorman Dep. at 106:3-8; 167:19-168:5; Trial Tr., July 27, 2010, at 182:18-24).

167. Dr. Dorman testified that he did not recall iMDsoft demonstrating any remote capabilities of the Schoenberg system at the meeting attended by Drs. Breslow and Rosenfeld. (Visicu's IC designation of Dorman Dep. at 88:16-91:5; 95:1796:7; Trial Tr., July 27, 2010, at 182:25-183:6).

168. Nor did Dr. Dorman recall "any specific recommendations made by them and I don't recall us ever referring back to any recommendation, suggestion, comment made by" iMDsoft. (Visicu's IC designation of Dorman Dep. at 103:21-104:13).

b. Cerner Has Failed to Prove Intent to Deceive Regarding MetaVision

169. The information Dr. Breslow and Dr. Rosenfeld learned about the MetaVision System at the November 1997 meeting led them to believe it was nothing different than the Emtek clinical information system ("CIS" or "SYS") they used at the time at Johns Hopkins. (*See* Trial Tr., July 28, 2010, at 259:18-24 (Dr. Rosenfeld); 264:11-14 (Dr. Rosenfeld); 339:1-10 (Dr. Breslow)).

170. The information Dr. Rosenfeld learned about the MetaVision System at the November 1997 meeting led him to believe that MetaVision was not at all remotely comparable to his later invention, the Visicu System. (Trial Tr., July 28, 2010, at 259:2-261:1).

171. Similarly, based on the November 1997 demonstration, Dr. Breslow thought the MetaVision System was just another ICU charting system that had no relevance to his later invention, and it never even occurred to him to disclose it to the PTO. (Trial Tr., July 28, 2010, at 338:3-10).

172. Cerner has failed to prove intent to deceive regarding the MetaVision System. *See* Facts 152-171, above.

173. At the November 1997 meeting, Dr. Schoenberg did not provide any documents or other materials to Dr. Breslow or Dr. Rosenfeld describing the MetaVision System. (Visicu's IC designation of Schoenberg Dep. at 247:3-7).

174. Dr. Schoenberg never gave Dr. Breslow or Dr. Rosenfeld a copy of any patent application. (Visicu's IC designation of Schoenberg Dep. at 247:3-10; Trial Tr., July 28, 2010, at 297:23-298:1). Nor did Dr. Schoenberg mention the patent. (Visicu's IC designation of Schoenberg Dep. at 247:3-10; Trial Tr., July 28, 2010, at 182:13-17).

175. Dr. Dorman testified that he did not recall any mention of iMDsoft's patent application at any of the meetings with Johns Hopkins' faculty. (Visicu's IC designation of Dorman Dep. at 165:16-21).

176. Dr. Schoenberg's Patent Cooperation Treaty ("PCT") application *was not filed* until December 29, 1997 – more than six weeks after the November 11, 1997 meeting involving Dr. Breslow and Dr. Rosenfeld. (PTX 197 (U.S. Patent No. 6,322,502 to Schoenberg et al.)) (identifying on its face page the Dec. 29, 1997 PCT filing date and the July 9, 1998 PCT publication date of the Schoenberg PCT Publication WO98/29790)).

177. Similarly, Dr. Schoenberg's PCT application *was not published* until July 9, 1998 – nearly eight months after the November 11, 1997 meeting. (*See* PTX 197 (U.S. Patent No. 6,322,502 to Schoenberg et al.) (identifying on its face page the Dec. 29, 1997 PCT filing date and the July 9, 1998 PCT publication date of the Schoenberg PCT Publication WO98/29790)).

178. Cerner has failed to prove that either Dr. Breslow or Dr. Rosenfeld had knowledge of the Schoenberg PCT Application.

179. Cerner has failed to prove that either Dr. Breslow or Dr. Rosenfeld withheld the Schoenberg PCT Application from the PTO with the specific intent to deceive.

3. Schoenberg and the '708 Patent

180. During prosecution of Visicu's '708 patent application, Visicu disclosed to the PTO the Schoenberg PCT publication. (PTX 600 at VIS00252525-26 and VIS00252699-700). Cerner has failed to come forward with any information regarding the MetaVision System not found in that application. Accordingly, there can be no inequitable conduct with respect to the '708 patent without reference to the prosecution of the '656 patent. *Agfa Corp. v. Creo Prods.*, 451 F.3d 1366, 1379 (Fed. Cir. 2006); *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1230 (Fed. Cir. 2007) ("[I]nequitable conduct with respect to one or more patents in a family can infect related applications."); *Fox Indus., Inc. v. Structural Pres. Sys., Inc.*, 922 F.2d 801, 803-804 (Fed. Cir. 1990) ("A breach of the duty of candor early in the prosecution may render unenforceable all claims which eventually issue from the same or a related application.").

E. Conclusion

181. Cerner has failed to prove by clear and convincing evidence that anyone substantively involved in the prosecution of the '656 and '708 patents withheld any material information with the specific intent to deceive the PTO.

WHEREFORE, for the reasons stated herein, Cerner's Claim of Inequitable Conduct is DENIED.

s/ Gary A. Fenner
Gary A. Fenner, Judge
United States District Court

DATED: January 4, 2011